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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
BARNHART, LORA ELIZABETH	
ART UNIT	**PAPER NUMBER**
1651	

DATE MAILED: 10/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/755,392	OTTO, ROEL	
	Examiner	Art Unit	
	Lora E. Barnhart	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 August 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The amendment received 8/30/05 with the Request for Continued Examination amending claims 1, 9, and 10 is acknowledged. Claims 1-10 are pending.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. Prior art references can be found in a prior Office action, unless otherwise noted.

Claim Objections

Claims 1-10 are objected to because of the following informalities: Claim 1 should begin with the word "A", as in "A process for preparation." Claims 2-10 should begin with the word "The", as in "The process of claim 1." Appropriate correction is required.

Claim Rejections - 35 USC § 112

Claims 1-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites a substrate comprising "a smaller amount of hexose monomers than pentose monomers", which is confusing. It is not clear whether the claim refers, for example, to a substrate comprising several types of pentose monomers and only one type of hexose monomer (*i.e.* a substrate comprising only glucose, fructose, arabinose, and xylose in arbitrary amounts), or, for example, to one that has more pentose monosaccharide molecules than hexose monosaccharide molecules in total (*i.e.* a

substrate comprising 6% fructose and 2% glucose, but no other monosaccharides). Clarification is required.

Because claims 2-10 depend from indefinite claim 1 and do not clarify the point of confusion, they must also be rejected under 35 U.S.C. 112, second paragraph.

Claim Rejections - 35 USC § 102

Claims 1 and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by Wiesenberger et al. (1987, U.S. Patent 4,702,922; reference A) taken in light of Low (1997, http://www.chem.agilent.com/cag/peak/peak2-97/article1.html; Agilent Technologies online article; reference U). The claims are drawn to a method of preparing lactic acid or lactate comprising homolactically and anaerobically fermenting a pentose-containing substrate by a moderately thermophilic *Bacillus* species to form lactic acid or lactate, wherein said substrate comprises a lesser amount of hexose monomers than pentose monomers. In some dependent claims, the substrate comprises glucose.

Wiesenberger et al. teach *Lactobacillus* sp. DSM 3174, which is facultatively anaerobic and undergoes homofermentative production of lactic acid from glucose. Wiesenberger et al. also teach that the DSM 3174 strain ferments apple juice to lactic acid at 33°C (Table II). Low is cited as evidence that apple juice contains the monosaccharides fructose and glucose (page 1, paragraph 3), and more specifically, approximately 6% fructose monomers and 2% glucose monomers (see table, page 3, lines PAJ-1 and PAJ-2).

Claim Rejections - 35 USC § 103

Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Green et al. (PCT '601) in view of Payot et al. The claims are drawn to a process for homolactically fermenting lactic acid or lactate using a moderately thermophilic *Bacillus* species from a pentose-containing substrate that comprises a smaller amount of hexose monomers than pentose monomers (and which contains glucose, xylose, or arabinose in some dependent claims). In some dependent claims, the bacteria are *Bacillus coagulans* or *Bacillus smithii*. In some dependent claims, the lactic acid and the bacteria are separated from the vessel in which fermentation occurs. The phrase "which ferment anaerobically" in claim 1 is interpreted to refer to the process of fermentation itself, not to the bacteria.

Green et al. teach a process for using *B. coagulans* J44 and *B. smithii* J30 to ferment lactic acid from a chemically defined medium (i.e. containing only salts, vitamins, buffers and amino acids in addition to a chosen carbohydrate source, said sources including glucose, xylose and arabinose, *inter alia*) in microaerophilic conditions (p.7-10). Green et al. further teach that said lactic acid is the majority product of said fermentation (Table 1). Green et al. do not specifically teach said fermentation under anaerobic conditions, nor do they teach separation steps for the biomass or the produced lactic acid.

Payot et al. teach that at a given pH, the production of lactic acid by *B. coagulans* increases significantly (Table 5). Additionally, in the process of Payot et al., the *B. coagulans* biomass is separated from the culture medium comprising fermented lactic

acid (Figure 8). Later in this process, lactic acid is separated from the other components of said culture medium using high-performance liquid chromatography (p.192, column 2, paragraph 1).

One of ordinary skill in the art would have had a reasonable expectation of success in making said substitutions because it is known that *B. coagulans* ferments pentose sugars to lactic acid under anaerobic conditions, and because it is well known in the art to separate fermentation products from the culture medium for later applications.

The skilled artisan would have had a further reasonable expectation of fermenting xylose or arabinose with a mixture of *B. coagulans* and *B. smithii* because Green et al. teach that both strains ferment lactic acid from xylose and arabinose (Table 1). The skilled artisan would have been motivated to combine the two strains in order to increase the yield of lactic acid. It is well established that duplicating components with similar functions within a composition is obvious; see *In re Harza*, 274 F.2d 669, 124 USPQ 378 (CCPA 1960) and M.P.E.P. § 2144.04.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to substitute the anaerobic conditions and separation steps of Payot et al. into the lactic acid production of Green et al. because *B. coagulans* produces more lactic acid under said conditions. Additionally, it is industrially desirable not only to produce optically pure lactic acid, but also to collect it for later applications. The skilled artisan would have been motivated to make said modifications because efficient production and collection of lactic acid from new sugar sources, e.g. pentoses,

would increase the amount of lactic acid able to be produced from carbon sources like molasses that previously could not be utilized fully.

Thus, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made.

Applicant has alleged that Payot et al. does not teach a substrate comprising a smaller amount of hexose monomers than pentose monomers (Remarks, page 10, paragraph 3). Applicant further urges that Payot teaches that biomass increases with aeration but does not teach anaerobic fermentation (*ibid.*). These arguments have been fully considered, but they are not persuasive.

Payot et al. was relied upon solely for the teachings regarding anaerobic lactic acid fermentation of *B. coagulans* and of separation and purification steps after said fermentation. The examiner concedes that the molasses substrate of Payot et al. does not fulfill the requirements of the instantly claimed substrate, but this fact is immaterial to the instant objection. The bacteria of Green et al. were grown on chemically defined media, not molasses (page 7, paragraph 4).

The phrase in question regarding anaerobic fermentation is at page 196, column 1, lines 13-16 of Payot et al.:

> Biomass increased under aerobic conditions, but **lactic acid concentration dramatically decreased**. This distinctive feature was described for B.sp.SHO- I by Ohara and Yahata in 1996 and was also confirmed by this experiment. (emphasis added by examiner)

The examiner agrees that Payot et al. teach that biomass increases when *B. coagulans* is grown under aerobic conditions but urges that Payot et al. also teach that lactic acid production by the same bacteria increases under anaerobic conditions. If

lactic acid concentration "dramatically decreased" when the bacteria were grown aerobically, then logical reasoning dictates that under anaerobic conditions, lactic acid concentration was relatively high. As such, Payot et al. teach that anaerobic fermentation of lactic acid by *B. coagulans* is preferable.

Claims 1-10 are also rejected under 35 U.S.C. 103(a) as being unpatentable over Wiesenberger et al. (reference A) taken in view of Low (reference U), Payot et al., and Sabinsa Corp. (reference V). The claims are drawn to a process for homolactically fermenting lactic acid or lactate using a moderately thermophilic *Bacillus* species from a pentose-containing substrate that comprises a smaller amount of hexose monomers than pentose monomers (and which contains glucose, xylose, or arabinose in some dependent claims). In some dependent claims, the bacteria are *Bacillus coagulans* or *Bacillus smithii*. In some dependent claims, the lactic acid and the bacteria are separated from the vessel in which fermentation occurs. The phrase "which ferment anaerobically" in claim 1 is interpreted to refer to the process of fermentation itself, not to the bacteria.

As discussed above, Wiesenberger et al. teach *Lactobacillus* sp. DSM 3174, which is facultatively anaerobic and undergoes homofermentative production of lactic acid from glucose. Wiesenberger et al. also teach that the DSM 3174 strain ferments apple juice to lactic acid (Table II). Low is cited as evidence that apple juice contains the monosaccharides fructose and glucose (page 1, paragraph 3), and more specifically,

approximately 6% fructose monomers and 2% glucose monomers (see table, page 3, lines PAJ-1 and PAJ-2; PAJ stands for "pure apple juice").

While Wiesenberger et al. teach that DSM 3174 does not ferment lactic acid from arabinose or xylose (column 5, lines 38-40), claims 2 and 4 do not require that lactic acid be fermented from these pentoses, and the claims do not require that no xylose or arabinose remain after the fermentation. The claims encompass an embodiment wherein DSM 3174 ferments lactic acid from apple juice to which xylose and arabinose (or, indeed, any other compound) have been added; all of the lactic acid is fermented from glucose and fructose naturally present in the juice, but the substrate comprises xylose and arabinose and, therefore, satisfies the requirements of claims 2 and 4.

Wiesenberger et al. do not teach fermenting lactic acid with DSM 3174 on chemically defined medium or in combination with another lactic acid-producing microorganism, and Wiesenberger et al. do not teach separating the bacteria from the apple juice after fermentation or purifying lactic acid from the fermentation broth.

While Wiesenberger et al. are silent as to the removal of bacteria after fermentation of apple juice, they do teach separating the bacteria from grape juice after fermentation (Example 2). The selection of juice for fermentation as it pertains to separating the bacteria from the juice after said fermentation clearly would have been a routine matter of optimization on the part of the artisan of ordinary skill, said artisan recognizing that Wiesenberger et al. teach that bacteria can be separated from fruit juice (Example 2). A holding of obviousness over the cited claims is therefore clearly required.

A person of ordinary skill in the art would have had a reasonable expectation of success in culturing DSM3174 in a defined medium because Wiesenberger et al. teach growing DSM 3174 in MRS broth (column 5, lines 43-44). The skilled artisan would have been motivated to grow DSM 3174 in a chemically defined medium in order to control the conditions of fermentation.

The skilled artisan would have had a further reasonable expectation of fermenting xylose or arabinose with a mixture of *Lactobacillus* spp. DSM 3174 with another lactic acid-producing microorganism, for example *Lactobacillus* spp. DSM 3173, because Wiesenberger et al. teach that both strains ferment lactic acid from xylose and arabinose (column 6, lines 25-38; Table II). The skilled artisan would have been motivated to combine the two strains in order to increase the yield of lactic acid. It is well established that duplicating components with similar functions within a composition is obvious; see *In re Harza*, 274 F.2d 669, 124 USPQ 378 (CCPA 1960) and M.P.E.P. § 2144.04.

The Patent and Trademark Office is not equipped to conduct experimentation in order to determine whether or not applicants' bacterial species (*i.e. Bacillus coagulans* and *Bacillus smithii*, in claim 3) differ, and if so to what extent, from the strains discussed in Wiesenberger et al. Accordingly, it has been established that the prior art *Lactobacillus* species, which has the same genus classification as *Bacillus coagulans* (which was originally identified as *Lactobacillus sporogenes*; see Sabinsa Corp., reference V, especially page 1, paragraphs 1-2) and shares the property of being able to produce lactic acid, demonstrates a reasonable probability that it is either identical or

sufficiently similar to the claimed species that whatever differences exist are not patentably significant. Therefore, the burden of establishing novelty or unobviousness by objective evidence is shifted to applicants. Clear evidence that the bacteria of the cited prior art do not possess a critical characteristic that is possessed by the claimed bacteria, would advance prosecution and might permit allowance of claims to applicants' method of using said bacteria.

It would therefore have been obvious to a person of ordinary skill in the art at the time the invention was made to combine the DSM 3174 strain of Wiesenberger et al. with the DSM 3173 strain, because Wiesenberger et al. teach that they have similar functions, and combining components with similar functions does not represent an inventive step. It would have been further obvious to said skilled artisan at the time the invention was made to conduct the fermentation in chemically defined medium because Wiesenberger et al. teach that the bacteria grow in said medium, and using a defined medium gives more consistent fermentation yields than fruit juice because its components are controlled. Finally, it would have been further obvious to said skilled artisan at the time the invention was made to separate the bacteria from the substrate because Wiesenberger et al. exemplify such a separation.

Therefore, the invention as a whole would have been *prima facie* obvious to a person of ordinary skill at the time the invention was made.

No claims are allowed. No claims are free of the art.

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure

outlined in MPEP § 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 U.S.C. § 102 or 35 U.S.C. § 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is requested in response to this Office action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lora E. Barnhart whose telephone number is 571-272-1928. The examiner can normally be reached on Monday-Friday, 8:00am - 4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SANDRA E. SAUCIER
PRIMARY EXAMINER

Lora E Barnhart

leb